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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/102,865	06/23/98	RAJU S	P1096R1

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EXAMINER	
SCHWADRON,R	
ART UNIT	**PAPER NUMBER**
1644	17

DATE MAILED: 06/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/102,865	Raju
Examiner	**Art Unit**
Ron Schwadron, Ph.D.	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 4/30/2001

2a)☐ This action is **FINAL.** 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above, claim(s) 10-24 is/are withdrawn from consideratio

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-9, 25-29 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some* c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☐ Notice of References Cited (PTO-892)

16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18)☐ Interview Summary (PTO-413) Paper No(s). _____

19)☐ Notice of Informal Patent Application (PTO-152)

20)☐ Other:

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/30/2001 has been entered.

2. Claims 1-9,25-29 are under consideration. Claim 1 has been amended.

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b)

4. Claims 1-9,25-29 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7,10-16,20,35-39,41-44 of copending Application No. 09/183824. Although the conflicting claims are not identical, they are not patentably distinct from each other because while the two sets of claims differ in scope, both sets of claims encompass compositions/articles of manufacture that comprise the glycoprotein with the properties recited in claim 1 of the instant application. Therefore the two sets of claims would have been prima facie obvious to one of ordinary skill in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant has indicated that this rejection will be addressed by indication of allowable subject matter.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-9,25-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the recitation of "G1 or G0" in claim 1. The specification, second paragraph, page 14, defines "by-products" as "G0 and G1" and states that the amount of by-product does not exceed 10% by weight. Thus, the limitation of 10% by weight refers to the concentration of G1 and G0, not G1 or G0. There is no written description of the scope of the claimed invention in the specification as originally filed (eg. the claimed invention constitutes new matter).

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-5,25 stand rejected under 35 U.S.C. 102(b) as being anticipated by Kumpel et al. for the reasons elaborated in the previous Office Action. Applicants arguments have been considered and deemed not persuasive.

Kumpel et al. teach human monoclonal antibodies wherein substantially all of the oligosaccharide found on said antibody is G2 (see Table 1, columns 1-3, and page 149, column 1, first incomplete paragraph). Said antibodies are in composition form wherein they are contained

in a pharmaceutically acceptable carrier (eg. tissue culture media). The antibody 2B6 disclosed in Table 1 is an IgG1 antibody (see page 144, second column). The preparations are substantially homogenous for the glycoprotein because they contain monoclonal antibodies in serum free tissue culture media (see page 144, second column).

Regarding applicants comments, there is no actual disclosure in the specification as to what degree of purity is encompassed by the term "substantially all". Applicant's arguments refer to the definition of "substantially homogenous", not the definition of "substantially all". Regarding the limitation recited in the last two lines of claim 1, said limitation recites that the G1 or G0 oligosaccharide does not exceed 10%. In the preparation taught by Kumpel et al. the G0 does not exceed 10% for the 2B6 or JAC10 or BRAD-3/LD antibodies (see Table 1).

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1-9,25-29 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Kumpel et al. in view of Maras et al. (US Patent 5,834,251) and prior art disclosed in the specification (pages 1,2,19-21). Applicants arguments have been considered and deemed not persuasive.

Kumpel et al. teach human monoclonal antibodies wherein substantially all of the oligosaccharide found on said antibody is G2 (see Table 1, columns 1-3, and page 149, column 1, first incomplete paragraph). Said antibodies are in composition form wherein they are contained in a pharmaceutically acceptable carrier (eg. tissue culture media). The antibody 2B6 disclosed in Table 1 is an IgG1 antibody (see page 144, second column). Kumpel et al. teach that antibodies with substantially all G2 oligosaccharide have increased lysis of target cells in comparison to the same antibody which is produced in a manner that results in low levels of G2 (see Figure 3). Kumpel et al. do not teach the molecules of claims 6-9 or the claimed articles of manufacture. Maras et al. teach that B-1,4 Galactosyltransferase can be used to modify the oligosaccharide profile on a glycoprotein (see columns 12 and 16). Kumpel et al. teach that said enzyme is

involved in the production of G2 oligosaccharides (see abstract). The prior art recited in the specification (pages 1,2,19-21) discloses that the antibodies, immunoadhesions and chimeric molecules recited in claims 6-9 were known in the art, as was the clinical use of said molecules. It would have been prima facie obvious to one of ordinary skill in the art to have created G2 oligosaccharide versions of the art known molecules recited in claims 6-9 because Kumpel et al. teach that antibodies with substantially all G2 oligosaccharide have increased lysis of target cells in comparison to the same antibody which is produced in a manner that results in low levels of G2 and Maras et al. teach that B-1,4 Galactosyltransferase can be used to modify the oligosaccharide profile on a glycoprotein (eg. to produce G2 oligosaccharide glycoproteins). One of ordinary skill in the art would have been motivated to do the aforementioned in order to produce G2 versions of the aforementioned glycoproteins for potential clinical evaluation. Said G2 glycoproteins would have been produced as the claimed articles of manufacture for use in clinical trials.

Regarding applicants comments, Kumpel et al. teach that antibodies with increased G2 oligosaccharide have increased lysis of target cells in comparison to the same antibody which is produced in a manner that results in low levels of G2 (see Figure 3). Kumpel et al. teach that "The "hypergalactosylated" anti-D (LD BRAD-3) promoted greater FcγRI- and FcγRIII- mediated lysis of erythrocytes in ADCC assays than the anti-D with a lower galactose content (HD BRAD-3)(as shown in Figures 3 and 4)." (see page 149, first column, first complete paragraph). Regarding applicants comments, there is no actual disclosure in the specification as to what degree of purity is encompassed by the term "substantially all". Applicant's arguments refer to the definition of "substantially homogenous", not the definition of "substantially all". Regarding the limitation recited in the last two lines of claim 1, said limitation recites that the G1 or G0 oligosaccharide does not exceed 10%. In the preparation taught by Kumpel et al. the G0 does not exceed 10% for the 2B6 or JAC10 or BRAD-3/LD antibodies (see Table 1).

11. No claim is allowed.

12. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP ~~1800~~ 1600

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644